REMARKS:

Claims 1-10 are in the case and presented for consideration.

Claim Rejections - 35 USC § 112

Claims 1 and 6 are rejected as being indefinite. In particular, claims 1 and 6 are objected for including the expression "each separately". Corrections have been made to the claims and they are all now believed to be in proper form.

Claim Rejections - 35 USC § 102

Claims 1-2 are rejected as being anticipated by US Patent 6,451,365 to King. Claim 1 has been amended and is believed to by novel over King.

No new matter has been added since the amended claims are based on the claims and specification as originally filed, particularly on claims 1, 3 and 4 and on paragraph [0024].

King discloses an antibacterial composition comprising: (a) a first component which is at least one gram positive bacteristatic or bactericidal compound selected from the group consisting of lantibiotics, pediocin and lacticin class bacteriocins, and lytic enzymes; and (b) a second component which is at least one compound selected from the group consisting of hop acids and hop acids derivatives. This composition provides excellent antibacterial properties, especially against bacteria of the listeria genus, showing an antibacterial efficacy that dramatically surpasses the antibacterial efficacy of the individual components (lines 31-42 of column 4 of King). The composition can be applied on the exterior surface of a food product (lines 55-59 of column 8) or to food packaging materials

or casings that are then applied to the food surface (lines 1-4 of column 9). Among many others, the food product can be a meat product such as fat containing cooked meats (lines 38-47 of column 8).

The method of amended claim 1 of the present application, however, differs fundamentally from the method of King in that the <u>hop-based components are used as the only bactericidal component</u>, as indicated in paragraph [0024] of specification of the present application.

Therefore claim 1 fulfils the requirements of novelty and so to does claim 2 which depends from amended claim 1.

King teaches a method for reducing gram positiva bacteria in food products comprising the step of treating the food surfaces thereof with an antibacterial composition that comprises (1) a bacteristatic or bactericidal compound and (2) a hop-based component due to the synergistic effect of the two components. In fact, in Examples 1-5 the higher antibacterial efficacy of the combination is showed compared to that of the individual components (nisin and/or lysozyme + beta hop acids).

Consequently, in light of King, it would not be obvious for the skilled person to apply only one component of the synergistic combination of King in order to obtain a similar antibacterial effect against Listeria monocytogenes. Effectively, when comparing the results of Table 5 of King (Example 5: incorporation of nisin + hop acids into the cellulosic casing for preparing wieners) and those of Tables I and II of the present application (Examples 1 and 2: application of hop acids or hydrogenated hop acids on the inside of a cellulosic casing for preparing frankfurter sausages), it is observe that for a time range of

7-35 days, the Listeria counts decrease similarly in about 2 log.

Therefore claim 1 is also believed to fulfil the requirement of non-obviousness and so to does claim 2 which depends from new claim 1.

Claim Rejections - 35 USC § 103

Claims 1-10 are also held to be obvious over US Patent 5,573,801 to Wilhoit in view of US Patent 5,286,506 to Millis.

Wilhoit discloses an antimicrobial composition comprising a combination of (a) a Streptococcus-derived bacteriocin or a Pediococcus-derived bacteriocin or a synthetic equivalent; and (b) a chelating agent (lines 17-21 of column 4), even tough the use of bacteriocins alone is also claimed. This composition has unexpectedly good bactericidal properties against pathogenic bacteria such as Listeria monocytogenes (lines 21-23 of column 4 of Wilhoit) and may be applied, for example, to the inside of a cellulosic casing which may be stuffed with a food product such as a meat emulsion, for example, in order to contact the foodstuff with the agent (lines 23-32 of column 12).

The method of new claim 1 of the present application differs from the method of Wilhoit in that the bactericidal agent is a hop-based component and not a bacteriocin or a combination of a bacteriocin and a chelating agent.

The substitution of bacteriocins (disclosed in Wilhoit) for hop beta acids (disclosed in Millis) is not equivalent and therefore the combination to reach claim 1 is not obvious since:

- Bacteriocins are of protein nature and hydrophilic, while hop beta acids and hydrogenated hop beta acids are quite hydrophobic. This feature results into a low efficacy

in high fat content food products. Therefore, it can be unexpected that the substitution of bacteriocins for a hop beta acid leads to a similar effect.

- Size and molecular weight of both compounds are quite different as bacteriocins are polypeptides and hop beta acids are complex isoprenoids.
- Allergenicity and the possible resistance appearance, typical of bacteriocins, will not be so relevant for hop beta acids since their molecular weight is lower.
- The antibacterial spectrum of both are different
- Bacteriocins can be inactivated during the thermal treatment when cooking the meat product, while the hop beta acids retain their antibacterial activity during it.
- Prices and simplicity of purification are also quite different.

Millis discloses a process comprising applying a composition containing 6 to 100 ppm of beta-acids as extracted from hops to a solid food product to incorporate from 6 to 50 ppm of beta-acids in said food product to prevent growth of Listeria in said food product. Among these solid foods processed meats are mentioned (lines 26-29 of column 3 of Millis), even though there is no example illustrating this application, and only the antibactericidal effect of the composition is showed in liquid cultures (Mueller Hinton broth and brain-hearth broth) (Examples 2-3).

The method of claim 1 of the present application thus differs from the method of Millis in that the bactericidal agent is at least one hop-based component selected from a hop extract, a hydrogenated hop extract, hop alpha acids, hop beta acids, hydrogenated hop acids and derivatives of hop acids or their resins.

The applicant considers that the present invention corresponds to an extension of

the object of Millis, since this only mentions the use of beta-acids and their derivatives, while the present invention considers the application of a series of compounds derived from hops, which also present antimicrobial activity (greater than that of beta acids) and are not referred to nor suggested in document Millis.

These compounds derived from hops are specified in document US Patent 5,455,038 to Barney (cited in paragraph [0021] of specification) in which the antimicrobial activity of hop derivatives, such as hexahydrocolupulone or tetrahydroisohumulone, is demonstrated or in US Patent 6,326,185 (cited in paragraph [0022] of specification) in which tetrahydroisoalpha acids and also hexahydroalpha acids are used as antimicrobial agents in beer yeast.

Additionally, the method of claim 1 of the present application differs from the method of Millis in that the antibacterial composition is applied to the internal surface of a cellulosic casing used to make sausages, and is not applied directly to the product or just tested in a liquid culture.

In relation to the use of cellulosic casings, the applicant considers that the application of the composition using cellulosic casings disclosed in Wilhoit is not equivalent to the direct application of the composition to the food product disclosed in Millis since in the production of a cellulosic casing containing hop-based components the following aspects must be taken into account:

- The compatibility of the hop-based components with the cellulose material of casing and with the additives incorporated therein (oils or peeling agents, for example).
- The possible diffusion or immobilization of the components within the cellulosic casing matrix.

- The effect of the components on the pH of the cellulosic casing (with the risk of possible hydrolysis of the cellulosic chains when the pH obtained is not appropriate).
- The amount of the transferred components present in the inside of the cellulosic casing to the food product (kinetics of transference over time, percentage of effective transference of antimicrobial agents from the casing to the food).

Thus, the application to the cellulosic casings is not equivalent to direct application to the food product so that there is no obvious reason to combination the teachings of these reference to reach claim 1 under 35 USC § 103.

Additionally, the applicant considers that the specific use of a cellulosic casing presents several different characteristics compared to simply immersing the food product in an antimicrobial bath:

a) The antibacterial component should resist the cooking process since it is in contact with the food product and then is submitted to the same heat treatment processes (cooking, drying etc.) as the food product is.

b) The antibacterial component should be transferred from the casing to the food. In the case of the bath, this phenomenon of transfer from the bath to the food occurs easily and without impediments. In the case of a casing containing the antibacterial component, this should migrate from the casing to the product. Moreover, in the case of cellulosic casings, this migration is almost impeded for high molecular weight products (higher than 13,000 Dalton) and for hydrophobic compounds, which hardly diffuse through the hydrophilic cellulosic matrix. Therefore, this kind of compounds cannot be used to

impregnate the cellulosic casing in this antimicrobial application since, as they remain in the cellulosic casing, the antimicrobial protection is only conferred to the casing (this is desired in some casings to discourage mould formation), but the protection is not conferred to the food inside the casing. If these compounds are to be used, they should be used to coat the interior surface of the casings, on the surface in direct contact with the food, to ensure that the casing does not impede transferring these antimicrobial compounds to the food.

c) The transference of the antibacterial component to the food presents certain special characteristics in the case of cellulosic casings. In the case of a food packaging that contains an antimicrobial agent, a continuous and sustained transfer of the antibacterial component to the food is preferable, in order to achieve a continuous microbial inhibition. In some cases the food packaging is in contact with the food to be protected throughout its entire useful life. In the case of a cellulosic casing, the contact is temporary, starting when the casing is filled with the meat paste until it is cooked (and optionally smoked) in this casing; after the cooking process, and when the surface layers of the sausage have formed a coagulated protein layer able to ensure the integrity of the sausage, the cellulosic casing is cut and removed and then the sausages are packed in packets of several units for sale to the consumer. In this case, transfer of the antimicrobial agent should take place in the short period of time during which the sausage and the cellulosic casing (which acts as a temporary mold during the cooking process) are in contact, transferring to the sausages the antimicrobial capacity against possible subsequent contamination, and not in a slow sustained mode as occurs for other food packaging.

d) The hydrophilic structure of the cellulosic casing, permeable to hydrophilic compounds, should prevent the possible diffusion of the antimicrobial agent to outside the casing (which would result into a reduction of the antimicrobial activity transferred to the food).

e) The material of the casing should not interfere with the function of the casing, which must maintain its physical properties (stability, sausage diameter, stick rigidity, good peeling etc.). For example, plastic materials are considered to be essentially inert against food products and, hence, also against the antimicrobial components. In the case of cellulosic casings, which are sold in a highly compressed form as folded sticks, it is not easy to imagine how an antimicrobial component that exerts its inhibitory activity in a bath, has the same effect as when added to a cellulosic casing, since the possible interaction between both components must be taken into account. Hence, this interaction can cause the folds of the stick to adhere together, or can affect the diameter of the sausage, or its resistance to traction, making the functionality of the cellulosic casing non-viable. Similarly, the pH characteristics or the components themselves can break down the structure of the cellulosic casing (with the risk of possible hydrolysis of the cellulosic chains if the pH obtained is not appropriate) or the other sausage ingredients (such as ingredients to facilitate peeling which are also added to the sausage wall), interfering with the functionality of the casing.

Hence, the combination of, Casing + antimicrobial agent = antimicrobial casing + interaction means that the effect of an antimicrobial compound applied to the surface of the food product will not necessarily produce a useful antimicrobial casing, such as the

cellulosic casing used in the said invention.

Finally, it would not be so obvious for the skilled person to use the hop beta acids disclosed in Millis instead of the composition of Wilhoit (bacteriocin + chelating agent) for being applied on an inside surface of a cellulosic casing used in the production of meat products in order to prevent an appearance and growth of gram-positive bacteria in such meat products.

Effectively, Millis, published in 1994, mentions the possibility of using hop beta acids in solid foods such as processed meats, even if it does not illustrate such application. However, a subsequent document of the art (WO 01/06877 of King et al., published in 2001 and cited in paragraph [0023] of specification) teaches that it is not possible to control Listeria in fat containing products such as meats and sausages employing only hop beta acids. In fact, the later patent of King et al. (US Patent 6,451,365 published in 2002) teaches the use of hop-based components combined with a bacteriocin for being applied to meat products having a high fat content.

In the light of the above comments, it is believed that the claims of present application meets the requirements of un-obviousness, since the composition and the method of the present application does not appear evident from the combination of Wilhoit and Millis to a person of ordinary skilled in the art.

Accordingly, the application and claims are believed to be in condition for allowance, and favorable action is respectfully requested.

No new matter has been added and if any issues remain which may be resolved by

telephonic communication, the Examiner is respectfully invited to contact the undersigned at the number below, if such will advance the application to allowance.

Respectfully submitted,

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